50. The recombinant vaccinia virus of claim 42, ~~wherein the polypeptide~~ which is VP9 ~~an antigen~~.

51. A method for producing a polypeptide comprising providing a recombinant vaccinia virus as claimed in claim 42, and infecting host cells with the recombinant vaccinia virus under conditions suitable for expression of the polypeptide.--

Please cancel claims 22 and 24 to 32, without prejudice.

REMARKS

Reconsideration and withdrawal of all issues of the February 15, 1995 Office Action, adding this application with claims 33 to 51 to Interference No. 103,399, designating claims 33 to 51 as corresponding to the Count, substituting the Count with claim 42 herewith, and, redeclaring the Interference with Paoletti as Senior Party, are respectfully requested.

Claims 22 and 24 to 32 are cancelled without prejudice so as to moot all issues of the Office Action. No admissions are made. Attached as Exhibit A is a copy of an Information Disclosure Statement not mentioned in the Office Action calling the Interference to the Examiner's attention.

Attached as Exhibit B is a copy of Moss' claims involved in the Interference. Claim 7 of Paoletti et al., U.S. Patent No. 4,603,112 ("the '112 Patent") is presently designated as corresponding to the Count, Moss' present claim 44; and, as set forth in the attached Exhibit C, concurrently filed Paoletti motions (without Exhibits), Moss' claim 44 fails to meet the

requirements of 35 U.S.C. §102/103, and 112, first and second paragraphs.[1] Further, as shown in Exhibit D, Paoletti's motion (without Exhibits) to have claim 7 designated as not corresponding to the Count, claim 7 is of different scope than whatever Moss may be claiming.

Thus, Paoletti presents claims 33 to 51 herewith, believed to be interfering with Moss' claims and, to be otherwise allowable as described and enabled in USSN 334,456. And, Paoletti believes that claim 42 should be the Count in the Interference ("Proposed Count A"). Paoletti should also accordingly be Senior Party, as Paoletti is entitled to a December 24, 1981 filing date.

Paoletti hereby identifies new claims 33 to 51 of pending U.S. application Serial No. 08/228,926, filed April 18, 1994, as corresponding to the Count and Proposed Count A. Paoletti applies the terms of the pending Paoletti claims to the terms of Paoletti's pending and predecessor applications in an unbroken lineage to USSN 334,456, filed December 24, 1981.

It is noted that USSN 08/228,926 was filed as a continuation of application Serial No. 07/881,995, filed May 4, 1992, as a divisional of application Serial No. 537,882, filed June 14, 1990, now U.S. Patent No. 5,110,587 ("the '587 Patent"); USSN 537,882 was a continuation of application Serial No. 90,209

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[1] The Examiner's attention is also called without prejudice or admission to Moss claim 57 vis-a-vis issues in the February, 15, 1995 Office Action concerning protein isolation being unpredictable: Such issues should be reconsidered and withdrawn or, applied as to Moss.

filed August 27, 1987 as a divisional of application Serial No. 622,135, filed June 19, 1984, now U.S. Patent No. 4,722,848 ("the '848 Patent"); USSN 622,135 was filed as a continuation-in-part of application Serial No. 446,825, filed December 8, 1982 (now the '112 Patent); and USSN 446,825 was filed as a continuation-in-part of application Serial No. 334,456, filed December 24, 1981, now U.S. Patent No. 4,769,330 ("the '330 Patent").

Thus, there are three specifications: The USSN 622,135 specification or the '848 Patent (the text of which is also the text of present application 08/228,926, USSN 07/881,995, USSN 537,882, also the '587 Patent, and USSN 90,209), the USSN 446,824 specification or the '112 Patent, and, the USSN 334,456 specification or the '330 Patent. The text of the '330 Patent is substantially within the text of the '112 Patent and, the texts of the '330 and '112 Patents are in the '848 Patent.

Accordingly, applying the terms of Paoletti's claims 33 to 51 to the specifications of the '848, '112 and '330 Patents demonstrates support in an unbroken chain of applications to USSN 334,456, filed December 24, 1981 (such that Paoletti should also be Senior Party); and, applying the terms of claims 33 to 51 to the '330 Patent demonstrates support in an unbroken chain of applications from USSN 334,456 to USSN 08/228,926). Claims 33 to 51 are not broader than the claims of the '330 Patent and, are patentable over the prior art for the reasons of record during the prosecution of USSN 334,456.

The following Table demonstrates support for claims 33 to 51 in the '330 Patent (USSN 334,456), the '112 Patent (USSN 446,825), and the '848 Patent (present application and USSNs 07/881,995, 537,882, 90,209 and 622,135) (the Paoletti and Hruby Declarations are attached as Exhibits E and F).

TABLE

CLAIM	TERMS	DISCLOSURE IN		
		'330 PATENT	'112 PATENT	'848 PATENT
33	A plasmid comprising donor DNA not naturally occurring in vaccinia virus encoding a polypeptide foreign to vaccinia virus, said donor DNA present within a non-essential region of a segment of vaccinia virus DNA otherwise co-linear with portions of the vaccinia virus genome such that DNA from a non-essential region of vaccinia virus is flanking said donor DNA, and whereby when incorporated into vaccinia virus by in vivo recombination expression of the donor DNA is under vaccinia control.	Claim 4 (col. 28, l. 66 to col. 30, l. 8); claim 8 (col. 29, l. 19 to 31); see also col. 4, line 58 to col. 5, line 5, col. 5, l. 53 to 64; col. 9, l. 46 to 51 (e.g., pBR322 cut then ligated with vaccinia HindIII F to form pDP3; pDP3 subjected to partial restriction with BamHI so the BamHI site in HindIII F of pDP3 cleaved to form linear DNA which is then ligated with BamIII HSV TK fragment to form plasmid with BamHI HSV TK fragment flanked by vaccinia F gene fragments, i.e., pDP132 and pDP137, which are used in recombination to generate VP-1, VP-2, VP-3, VP-4, VP-5, VP-6). Claim 5 (col. 29, l. 9 to 12); see generally Figs. 3A-3C; col. 4, l. 58 to col. 6, l. 14, col. 8, l. 39 to col. 9, l. 5, col. 9, l. 46 to 51, (pDP132 and pDP137 contain flanking DNA sequences co-linear with vaccinia virus F fragment, except for presence of HSV TK gene; recombinants VP-1, VP-2, VP-3, VP-4, VP-5 and VP-6 generated from pDP132 and pDP137); Claim 6 (col. 29, l. 13 to 15); col. 3, l. 15 to 28;	Col. 6, line 6 to col. 6, line 21, col. 7, lines 1 to 12, col. 10, line 64 to col. 11, line 2; Figs. 3A-3C; col. 6, line 6 to col. 7, line 30, col. 9, line 55 to col. 10, line 22, col. 10, line 64 to col. 11, line 2; col. 3, lines 15 to 28, col. 2, line 64 to col. 3, line 2, col. 10, lines 15 to 16, col. 11, lines 25 to 28, col. 16, lines 8 to 12 and 21 to 38, and Paoletti and Hruby Declaration (disclosure similar to that of '330 Patent). Figs. 7A-11E, col. 16, line 47 to col. 22, line 52 (incorporating pBR322 into vaccinia HindIII F, generating vP9 and vP10 containing influenza HA antigen gene, infecting rabbits with vP9 and detecting antibodies to HA, generating vP11 and vP12 containing hepatitis B surface antigen coding; vP9 to vP12 generated via plasmids having donor DNA within non-essential region of segment of vaccinia virus DNA otherwise co-linear with portions of the vaccinia genome such that non-essential region DNA flanks the donor DNA whereby when in vaccinia there is expression under vaccinia control); See also Examples I-XII, XV-XIX, XXIV and XXV and Figs 15A-F (col. 24, lines 17 to col. 25, line 26) (note pDP202 and vP22).	Col. 6, line 23 to col. 6, line 39, col. 7, lines 19 to 30, col. 11, lines 14 to 20; Figs. 3A-3C, col. 6, line 23 to col. 7, line 48, col. 10, lines 5 to 40; col. 3, lines 20 to 34; col. 2, line 68 to col. 3, line 6, col. 10, lines 33 to 34, col. 11, lines 43 to 46, col. 16, lines 24 to 28 and 37 to 54, and Paoletti and Hruby Declarations (disclosure similar to that of '330 Patent). Figs. 7A to 11E, col. 16, line 63 to col. 23, line 16, Examples I-XII, XV-XIX, XXIV and XXV, Figs. 15A-F (col. 24, line 33 to col. 25, line 44 (similar to additional disclosure cited for '112 Patent). Figs. 16 to 19 col. 25, line 45 to col. 27, line 66 (plasmid pRW derived from pBR25, generation of vP53, vP59, vP60, expressing HA, HBSAg, HSVgD); Examples XXVI-XXXII.

CLAIM	TERMS	DISCLOSURE IN		
		'330 PATENT	'112 PATENT	'848 PATENT
33 (continued)		**(continued)** Claim 6 (col. 29, l. 13 to 15); col. 3, l. 15 to 28; note also region present in L-variant but deleted from S-variant or within HindIII F-fragment of vaccinia virus, where HSV TK inserted in VP-1, VP-2, VP-3, VP-4, VP-5, and VP-6); see also col. 2, line 63 to col. 3 line 1 (teaching incorporation of strong promoter), col. 8, lines 64 to 68 (teaching case promotion of transcription of HSV TK by promoter within F-fragment), col. 10, lines 7 to 10 (teaching expression under vaccinia control), co. 14, lines 58 to 62 (teaching applicability to other non-essential sites), col. 15, lines 3 to 20 (teaching alternate embodiment of inserting F-fragment with different exogenous DNA therein in place of HSV TK F-fragment, showing non-reliance on HSV TK DNA which functions in HSV and not vaccinia as promoter and is thus not a "promoter" recombinant vaccinia virus); Exhibits E and F (Hruby and Paoletti Declarations interpreting '330 Patent, including that col. 2, line 63 to col. 3, line 1 in view of col. 10, line 10 means that the "strong promoter" is a vaccinia promoter).		
34	The plasmid of claim 33 wherein the donor DNA comprises a herpes simplex virus TK gene.	See citation for claim 33.	See citation for claim 33.	See citation for claim 33.

CLAIM	TERMS	DISCLOSURE IN		
		'330 PATENT	'112 PATENT	'848 PATENT
35	The plasmid of claim 33 wherein the segment of vaccinia virus DNA otherwise co-linear with portions of the vaccinia virus genome is the HindIII F-fragment of the vaccinia virus genome.	See citation for claim 33.	See citation for claim 33.	See citation for claim 33.
36	The plasmid of claim 35 wherein for expression there is a promoter within the F-fragment.	See citation for claim 33.	See citation for claim 33.	See citation for claim 33.
37	The plasmid of claim 36 wherein the donor DNA comprises a BamHI TK gene of herpes simplex virus.	See citation for claim 33.	See citation for claim 33.	See citation for claim 33.
38	The plasmid of claim 34 wherein the segment of vaccinia virus DNA otherwise co-linear with portions of the vaccinia virus genome is the AvaI H-fragment of the vaccinia virus genome.		Examples XXIV and XXV. Figs. 15A-F, col. 24, line 17 to col. 25, line 26.	Examples XXIV and XXV. Figs. 15A-F, col. 24, line 33 to col. 25, line 44.
39	The plasmid of claim 35 which is pDP137.	See citation for claim 33.	See citation for claim 33.	See citation for claim 33.
40	The plasmid of claim 38 which is pDP202.		Examples XXIV and XXV. Figs. 15A-F, col. 24, line 17 to col. 25, line 26.	Examples XXIV and XXV. Figs. 15A-F, col. 24, line 33 to col. 25, line 44.

CLAIM	TERMS	DISCLOSURE IN		
		'330 PATENT	'112 PATENT	'848 PATENT
41	The plasmid of claim 33 wherein the polypeptide is an antigen.	See VP-2, VP-4, VP-6. Col. 3, l. 29 to 38 (modification of vaccinia virus by incorporation of exogenous genetic information illustrated by vaccinia virus having incorporated therein a gene of HSV responsible for production of thymidine kinase ("TK"), an enzyme (i.e., protein)); col. 12, 1. 34 to 66, col. 13, l. 21 to col. 14, l. 50; Examples XI-XII (expression of HSV TK gene by incorporating IDC* and by use of selective medium; HSV TK only TK gene present in VP-4, MTAGG selectively discriminates between organisms containing and expressing TK gene and those which do not (Selects for TK^+ and against TK^-; Example VIII), VP-4 survives on MTAGG and by hybridization is shown to contain HSV TK gene); col. 2, l. 9 to 15 (consequences of discovery of invention includes novel methods for vaccinating with vaccinia containing foreign DNA coding for antigens); see also col. 2, l. 20 to col. 3, l. 1; col. 3, l. 39 to 56 (if HSV TK gene introduced and expressed then other genes can be introduced and expressed);	Col. 3, lines 29 to 38; col. 13, line 51 to col. 14, line 16, col. 14, line 40 to col. 15, line 68; Examples XI-XII; col. 2, line 10 to col. 1, line 63 to col. 2, line 34, et seq. (similar disclosure to that of '330 Patent). See also citations for claim 33 (note vP9, vP10, vP11 and vP12, and, rabbit test).	See citations for claim 33. See also Fig. 20 (plot of antibody response), col. 27, line 67 to col. 28, line 60; Examples XXXII (determination of expression in rabbits via antibody response and challenge in mice).

CLAIM	TERMS	DISCLOSURE IN		
		'330 PATENT	'112 PATENT	'848 PATENT
41 (continued)		**(continued)** Col. 1, l. 62 to 65, col. 2, l. 32 et seq. (foreign DNA may be naturally occurring in organism other than vaccinia, including disease producing organisms; bacteria are disease producing organisms).		

CLAIM	TERMS	DISCLOSURE IN		
		'330 PATENT	'112 PATENT	'848 PATENT
42	A recombinant vaccinia virus comprising donor DNA not naturally occurring in vaccinia virus encoding a polypeptide foreign to vaccinia virus and a promoter operably linked to the donor DNA, and, which exerts functional control over the donor DNA, said donor DNA present within a non-essential region of a segment of vaccinia virus DNA otherwise co-linear with portions of the vaccinia virus genome such that the donor DNA is positioned within a non-essential region of the recombinant vaccinia virus, and, wherein there is expression of the donor DNA under vaccinia control.	Claim 4 (col. 28, l. 66 to col. 30, l. 8); claim 8 (col. 29, l. 19 to 31); see also col. 4, line 58 to col. 5, line 5, col. 5, l. 53 to 64; col. 9, l. 46 to 51 (e.g., pBR322 cut then ligated with vaccinia HindIII F to form pDP3; pDP3 subjected to partial restriction with BamHI so the BamHI site in HindIII F of pDP3 cleaved to form linear DNA which is then ligated with BamIII HSV TK fragment to form plasmid with BamHI HSV TK fragment flanked by vaccinia F gene fragments, i.e., pDP132 and pDP137, which are used in recombination to generate VP-1, VP-2, VP-3, VP-4, VP-5, VP-6). Claim 5 (col. 29, l. 9 to 12); see generally Figs. 3A-3C; col. 4, l. 58 to col. 6, l. 14, col. 8, l. 39 to col. 9, l. 5, col. 9, l. 46 to 51, (pDP132 and pDP137 contain flanking DNA sequences co-linear with vaccinia virus F fragment, except for presence of HSV TK gene; recombinants VP-1, VP-2, VP-3, VP-4, VP-5 and VP-6 generated from pDP132 and pDP137); Claim 6 (col. 29, l. 13 to 15); col. 3, l. 15 to 28;	Col. 6, line 6 to col. 6, line 21, col. 7, lines 1 to 12, col. 10, line 64 to col. 11, line 2; Figs. 3A-3C; col. 6, line 6 to col. 7, line 30, col. 9, line 55 to col. 10, line 22, col. 10, line 64 to col. 11, line 2; col. 3, lines 15 to 28, col. 2, line 64 to col. 3, line 2, col. 10, lines 15 to 16, col. 11, lines 25 to 28, col. 16, lines 8 to 12 and 21 to 38, and Paoletti and Hruby Declaration (disclosure similar to that of '330 Patent). Figs. 7A - 11E, col. 16, line 47 to col. 22, line 52 (incorporating pBR322 into vaccinia HindIII F, generating vP9 and vP10 containing influenza HA antigen gene, infecting rabbits with vP9 and detecting antibodies to HA, generating vP11 and vP12 containing hepatitis B surface antigen coding; vP9 to vP12 generated via plasmids having donor DNA within non-essential region of segment of vaccinia virus DNA otherwise co-linear with portions of the vaccinia genome such that non-essential region DNA flanks the donor DNA whereby when in vaccinia there is expression under vaccinia control); See also Examples I-XII, XV-XIX, XXIV and XXV and Figs 15A-F (col. 24, lines 17 to col. 25, line 26) (note pDP202 and vP22).	Col. 6, line 23 to col. 6, line 39, col. 7, lines 19 to 30, col. 11, lines 14 to 20; Figs. 3A-3C, col. 6, line 23 to col. 7, line 48, col. 10, lines 5 to 40; col. 3, lines 20 to 34; col. 2, line 68 to col. 3, line 6, col. 10, lins 33 to 34, col. 11, lines 43 to 46, col. 16, lines 24 to 28 and 37 to 54, and Paoletti and Hruby Declarations (disclosure similar to that of '330 Patent). Figs. 7A to 11E, col. 16, line 63 to col. 23, line 16, Examples I-XII, XV-XIX, XXIV and XXV, Figs. 15A-F (col. 24, line 33 to col. 25, line 44 (similar to additional disclosure cited for '112 Patent). Figs. 16 to 19 col. 25, line 45 to col. 27, line 66 (plasmid pRW derived from pBR25, generation of vP53, vP59, vP60, expressing HA, HBSAg, HSVgD); Examples XXVI-XXXII.

CLAIM	TERMS	DISCLOSURE IN		
		'330 PATENT	'112 PATENT	'848 PATENT
42 (continued)		**(continued)** Claim 6 (col. 29, l. 13 to 15); col. 3, l. 15 to 28; note also region present in L-variant but deleted from S-variant or within HindIII F-fragment of vaccinia virus, where HSV TK inserted in VP-1, VP-2, VP-3, VP-4, VP-5, and VP-6); see also col. 2, line 63 to col. 3 line 1 (teaching incorporation of strong promoter), col. 8, lines 64 to 68 (teaching case promotion of transcription of HSV TK by promoter within F-fragment), col. 10, lines 7 to 10 (teaching expression under vaccinia control), col. 15, lines 3 to 20 (teaching alternate embodiment of inserting F-fragment with different exogenous DNA therein in place of HSV TK F-fragment, showing non-reliance on HSV TK DNA which functions in HSV and not vaccinia as promoter and is thus not a "promoter" in a recombinant vaccinia virus); Exhibits E and F (Hruby and Paoletti Declarations (attached as Exhibits, interpreting '330 Patent, including that col. 2, line 63 to col. 3, line 1 in view of col. 10, line 10 means that the "strong promoter" is a vaccinia promoter).		
43	The recombinant vaccinia virus of claim 42 wherein the donor DNA comprises a herpes simplex virus TK gene.	See citation for claim 42.	See citation for claim 42.	See citation for claim 42.

CLAIM	TERMS	DISCLOSURE IN		
		'330 PATENT	'112 PATENT	'848 PATENT
44	The recombinant vaccinia virus of claim 42 wherein the segment of vaccinia virus DNA otherwise co-linear with portions of the vaccinia virus genome is the HindIII F-fragment of the vaccinia virus genome.	See citation for claim 42.	See citation for claim 42.	See citation for claim 42.
45	The recombinant vaccinia virus of claim 44 wherein the promoter is within the F-fragment.	See citation for claim 42.	See citation for claim 42.	See citation for claim 42.
46	The recombinant vaccinia virus of claim 45 wherein the donor DNA comprises a BamHI TK gene of herpes simplex virus.	See citation for claim 42.	See citation for claim 42.	See citation for claim 42.
47	The recombinant vaccinia virus of claim 43 wherein the segment of vaccinia virus DNA otherwise co-linear with portions of the vaccinia virus genome is the AvaI H-fragment of the vaccinia genome.		Examples XXIV and XXV. Figs. 15A-F, col. 24, line 17 to col. 25, line 26.	Examples XXIV and XXV. Figs. 15A-F, col. 24, line 33 to col. 25, line 44.
48	The recombinant vaccinia virus of claim 44 which is vP2, vP4 or vP6.	See citation for claim 42.	See citation for claim 42.	See citation for claim 42.
49	The recombinant vaccinia virus of claim 47 which is vP22.		Examples XXIV and XXV. Figs. 15A-F, col. 24, line 17 to col. 25, line 26.	Examples XXIV and XXV. Figs. 15A-F, col. 24, line 33 to col. 25, line 44.

CLAIM	TERMS	DISCLOSURE IN		
		'330 PATENT	'112 PATENT	'848 PATENT
50	The recombinant vaccinia virus of claim 42 wherein the polypeptide is an antigen.	See VP-2, VP-4, VP-6. Col. 3, l. 29 to 38 (modification of vaccinia virus by incorporation of exogenous genetic information illustrated by vaccinia virus having incorporated therein a gene of HSV responsible for production of thymidine kinase ("TK"), an enzyme (i.e., protein)); col. 12, 1. 34 to 66, col. 13, l. 21 to col. 14, l. 50; Examples XI-XII (expression of HSV TK gene by incorporating IDC* and by use of selective medium; HSV TK only TK gene present in VP-4, MTAGG selectively discriminates between organisms containing and expressing TK gene and those which do not (Selects for TK^+ and against TK^-; Example VIII), VP-4 survives on MTAGG and by hybridization is shown to contain HSV TK gene); Col. 2, l. 9 to 15 (consequences of discovery of invention includes novel methods for vaccinating with vaccinia containing foreign DNA coding for antigens); see also col. 2, l. 20 to col. 3, l. 1; col. 3, l. 39 to 56 (if HSV TK gene introduced and expressed then other genes can be introduced and expressed);	Col. 3, lines 29 to 38; col. 13, line 51 to col. 14, line 16, col. 14, line 40 to col. 15, line 68; Examples XI-XII; col. 2, line 10 to col. 1, line 63 to col. 2, line 34, et seq. (similar disclosure to that of '330 Patent). See also citations for claim 33 (note vP9, vP10, vP11 and vP12, and, rabbit test).	See citations for claim 33. See also Fig. 20 (plot of antibody response), col. 27, line 67 to col. 28, line 60; Examples XXXII (determination of expression in rabbits via antibody response and challenge in mice).

CLAIM	TERMS	DISCLOSURE IN		
		'330 PATENT	'112 PATENT	'848 PATENT
50 (continued)		**(continued)** Col. 1, l. 62 to 65, col. 2, l. 32 et seq. (foreign DNA may be naturally occurring in organism other than vaccinia, including disease producing organisms; bacteria are disease producing organisms).		
51	A method for producing a polypeptide comprising providing a recombinant vaccinia virus as claimed in claim 42, and infecting host cells with the recombinant vaccinia virus under conditions suitable for expression of the polypeptide.	Claim 14 (col. 30, l. 15 to 18); Examples X and XII (use of BHK-21 (C-13) cells, i.e., Syrian hamster kidney cells, and CV-1, a green monkey kidney cell line; plaque purifying on CV-1 for in situ hybridization with ^{32}P-labelled Bam HSV TK, i.e., DNA of recombinant vaccinia replicated in eukarayotic cell and, sufficient quantity produced for hybridization); Claim 15 (col. 30, l. 19 to 20); Claim 18 (col. 30, l. 26 to 28); (plaques isolated from VP-4 infected human (line 143) TK$^-$ cells in presence of MTAGG means that infected cells expressed the HSV TK gene, i.e., TK, a protein). See also citations for claims 33, 41, 42 and 50.	Examples X and XII (same disclosure as in the '330 Patent); See also citations for claims 33, 41, 42 and 50 (not also Examples XV to XIX and XXIV and XXV, infecting cells with vP9, vP10, vP22, e.g., BHK-21, rabbits, CV-1.	See citations for claims 42 and 50.

Reconsideration and withdrawal of all issues of the February 15, 1995 Office Action, adding this application with claims 33 to 51 to Interference No. 103,399, designating claims 33 to 51 as corresponding to the Count, substituting the Count with claim 42 herewith, and, redeclaring the Interference with Paoletti as Senior Party, are respectfully requested.

Respectfully submitted,

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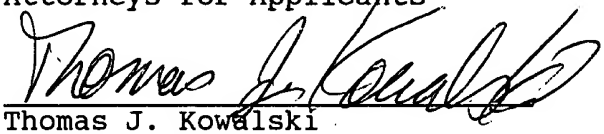

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